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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,320	01/31/2002	Jonathan S. Stamler	1818.1030-003	1921

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EXAMINER	
GUPTA, ANISH	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,320	STAMLER ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 28, drawn to method of determining the physiological effects of a composition comprising hemoglobin, classified in class 436, subclass 66.

II. Claim 3, drawn to delivering NO to tissue by administering dinitrosyl iron complex of hemoglobin, classified in class 514, subclass 2+

III. Claims 4-6, drawn to method of producing S-nitrosohemoglobin using oxygenated hemoglobin or oxygenated erythrocytes, classified in class 530, subclass 385.

IV. Claims 7-8, drawn to method of producing S-nitrosohemoglobin using deoxygenated hemoglobin or oxygenated erythrocytes, classified in class 530, subclass 385.

V. Claims 9-10, drawn to method of delivering NO to tissue by administering phosphate and hemoglobin, classified in class 514, subclass 2+.

VI. Claim 11, drawn to a method of trapping NO as iron nitrosyl-hemoglobin, by administering hemoglobin, phosphate and borate, classified in class 514, subclass 2+.

VII. Claim 12-14, drawn to method for effective NO delivery in a mammal administering hemoglobin in a physiologically compatible buffer, classified in class 514, subclass 2+.

VIII. Claim 15, drawn to method for treating sickle cell disease using hemoglobin, phosphate and NO gas inhalation, classified in class 514, subclass 2+.

IX. Claim 16 and 29, drawn to a method of treating sickle cell disease using inhaled Oxygen, inhaled NO and hemoglobin, classified in class 514, subclass 2+.

X. Claim 17, drawn to method of treating sickle cell disease using hemoglobin, phosphate, and inorganic nitrate, classified in class 514, subclass 2+.

XI. Claim 18, drawn to method of delivering NO to a mammal by manipulating erythrocytes with NO and administering the erythrocytes to a mammal, classified in class 424, subclass 93.73.

XII. Claim 19-20, drawn to a method of inhibiting NO release by using AE1 anion transport function inhibitor, classified in class 514, subclass 724+.

XIII. Claim 21, drawn to method of scavenging NO and free radicals in a mammal using AE1 anion transport function inhibitor, classified in class 514, subclass 724+.

XIV. Claim 22, drawn to a method of treating an inflammatory condition using AE1 anion transport function inhibitor, classified in class 514, subclass 724+.

XV. Claim 23, drawn to method of preserving red blood cells by dissolving NO gas to the composition, classified in class 514, subclass 2+.

XVI. Claim 24-25, drawn to method of decreasing the release of NO using an inhibitor for Carbonic anhydrase II activity, classified in class 514, subclass 601+.

XVII. Claim 26, drawn to method of treating a medical disorder mediated by NO by administering SNO-hemoglobin, classified in class 514, subclass 2+.

XVIII. Claim 27, drawn to method of restoring red blood cells in a mammal by administering red blood cells which having been treated with NO gas, classified in class 424, subclass 93.73.

The inventions are distinct, each from the other because of the following reasons:

All of the methods disclosed in the Groups above are independent and distinct from one another, in that they either, have different end points, us different compositions in the method, or facilitate different means for achieving a similar end point.

For example, method of Group I, involves an assay method to determine the physiological effects of hemoglobin. This method involves the use of EPR or UV spectral analysis. None of the methods of Group II-XVIII involve the use of such analytical methods. In fact, the methods of Group II-XVIII are devoted to administration methods which involve treatment of various conditions.

The method of Group II differs from every other method, in that it involves dinitrosyl iron complex of hemoglobin. None of the other methods disclose or use this complex of hemoglobin. Thus, the method is distrinct from all others.

The method of Group III and IV involve the production of S-nitrosohemoglobin using oxygenated hemoglobin or deoxygenated hemoglobin. None of the groups recited disclose a method of producing S-nirtorsohemoglobin. Group III and IV are distinct in that the source of production is different for each. Group III involves the use of oxygenated products while Group IV involves the use of deoxygenated products.

The method of Groups V and XI involve method of delivering NO, which is not taught by any other methods. These two methods are distinct from one another in that one method involves the use of hemoglobin and phosphate, while the other one involves the use of erythrocytes. Thus the methods are distinct.

The methods of Groups VIII-X all involve the treatment of sickle cell disease. A method that is distinct from every other method in that the patients are different and the end result is different from other methods. Further, the methods of VIII-X, even though drawn to sickle cell

disease, are distinct in that each method involves the administration of a distinct composition. One method involves the use of phosphate and NO gas while the other do not. Thus the methods are distinct.

Groups XII-IV are distinct in that the methods involve the use of AE1 anion transport function inhibitor, which are structurally distinct from any composition used in any other method. The methods themselves are distinct in that each method has a different end point. One method involves the inhibition of NO while the other method involves the scavenging of NO. Thus, presumably, different patients would be used for each method.

Groups XVI and XVII are both distinct since each method utilizes compounds that are not utilized by any other method. Inhibitor for Carbonic anhydrase II activity and SNO-hemoglobin are structurally distinct from any other compounds used in any other claim.

Finally, the remain groups, VI, VII, XIV, XVIII are distinct from each other and other methods in that each method has a different end point and utilize different compositions to achieve that endpoint. For example, group XV involves a method of preserving red blood cells. Although other methods might utilize erythrocytes, this is independent and distinct because the method is for preservation and not inhibition of NO, or production of a type of hemoglobin.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups I-XVIII is not required for each other, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group XII-XIV the using AE1 anion transport function inhibitor.

For Group XVI, the carbonic anhydrase II activity inhibitor disclosed in claim 25.

For Group XVII, the SNO-hemoglobin of a)-e).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 19-22, 24-26 generic.

Note, that if Applicants elect any one of Group XII-XIV, then applicants are requested to elect a single discloses species of AE1 anion transport function inhibitor.

Similarly, if Applicants elect group XVI, then applicants are requested to elect a single anhydrase II activity inhibitor.

Finally, if Applicants elect Group XVII, then applicant are requested to elect a single disclose SNO-hemoglobin recited in claim 26.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

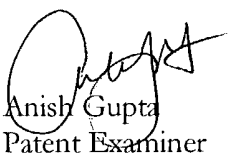
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta
Patent Examiner